

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.,)	
GILEAD SCIENCES IRELAND UC,)	
JANSSEN PRODUCTS, L.P., and)	
JANSSEN SCIENCES IRELAND)	
UNLIMITED COMPANY,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
APOTEX INC. and APOTEX CORP.,)	
)	
Defendants.)	

**PLAINTIFFS GILEAD SCIENCES, INC.’S, GILEAD SCIENCES IRELAND UC’S,
JANSSEN PRODUCTS, L.P.’S, AND JANSSEN SCIENCES IRELAND UNLIMITED
COMPANY’S COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, “Gilead”), and Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, “Janssen”) (all collectively, “Plaintiffs”), by their undersigned attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the U.S., Title 35, United States Code, against Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”). This action arises out of Apotex’s submission of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”).

2. Apotex seeks approval to market a generic copy of Janssen’s highly successful product, SYMTUZA®, containing a four-drug combination of darunavir, cobicistat, emtricitabine, and tenofovir alafenamide, prior to the expiration of U.S. Patent No. 10,039,718 (the “718 patent”) and U.S. Patent No. 10,786,518 (the “518 patent”) (together, the “Orange Book Patents-In-Suit”), and U.S. Patent No. 8,497,396 (the “396 patent”), U.S. Patent No. 9,428,473 (the “473

patent”), and U.S. Patent No. 9,115,100 (the “100 patent”) (together, the “COBI Patents-In-Suit”) (all patents collectively, the “Patents-In-Suit”). Plaintiffs attach hereto true and accurate copies of each of the Patents-In-Suit as Exhibits A-E.

PARTIES

Plaintiff Gilead

3. Plaintiff Gilead Sciences, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

4. Plaintiff Gilead Sciences Ireland UC is an Irish company, having its principal place of business at IDA Business & Technology Park, Carrigtohill, County Cork, Ireland.

5. Gilead is a research-based pharmaceutical company that invents, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for human immunodeficiency virus (“HIV”), hepatitis B virus (“HBV”), hepatitis C virus (“HCV”), hepatitis delta virus (“HDV”), liver diseases, serious cardiovascular and respiratory diseases, and cancer. Gilead’s portfolio of products includes treatments for HIV using the drugs cobicistat, emtricitabine, and tenofovir alafenamide. Gilead is the owner or co-owner of the Patents-In-Suit.

Plaintiff Janssen

6. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

7. Plaintiff Janssen Sciences Ireland Unlimited Company is an Irish corporation having its principal place of business at Barnahely, Ringaskiddy, County Cork, Ireland.

8. Janssen is an innovator pharmaceutical company that discovers, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for HIV/AIDS and cancer. Janssen markets SYMTUZA® in this District and throughout the United States. Janssen is the co-owner of the '518 patent and holds an exclusive license under the '718 patent for the commercialization of SYMTUZA®.

Defendants Apotex Inc. & Apotex Corp.

9. On information and belief, Apotex Inc. is a foreign corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

10. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 N. Commerce Parkway Suite 400, Weston, FL 33326.

11. On information and belief, Apotex, alone and through subsidiaries, affiliates, agents, and partners, manufactures, distributes, and/or imports generic copies of branded pharmaceutical products for sale and use throughout the United States, including in this District.

12. On information and belief, Apotex, alone and with subsidiaries, affiliates, agents, and partners, prepared and filed ANDA No. 217728 (the "Apotex SYMTUZA ANDA"), seeking approval to manufacture, import, market, and/or sell a generic copy of Janssen's SYMTUZA® product (the "Apotex SYMTUZA ANDA Product") in the United States, including in this District, if the FDA approves the Apotex SYMTUZA ANDA. On information and belief, Apotex is the holder of the Apotex SYMTUZA ANDA.

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 et seq., including §§ 271(e)(2), 271(a), 271(b), 271(c), and 271(g). This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

14. The Court also has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Plaintiffs and Apotex of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the Patents-In-Suit.

Apotex Inc.

15. On information and belief, this Court has personal jurisdiction over Apotex, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through subsidiaries, agents, and/or affiliates, Apotex Inc. regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including in Delaware. On information and belief, either directly or through subsidiaries, agents, and/or affiliates, Apotex Inc. has received more than 90 FDA approvals to market and sell pharmaceutical products throughout the United States, including in Delaware. On information and belief, Apotex Inc. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

16. On information and belief, Apotex Inc. markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Apotex Corp., a Delaware corporation that is registered to do business and has appointed an agent to accept service in

Delaware. On information and belief, Apotex Inc., through Apotex Corp., is licensed to sell generic pharmaceutical products in the State of Delaware pursuant to 24 Del. C. § 2540.

17. On information and belief, Apotex Inc. and Apotex Corp. operate and act in concert as an integrated, unitary business. On information and belief, Apotex Inc. and Apotex Corp. work in concert with respect to the manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in Delaware.

18. This Court also has personal jurisdiction because Apotex Inc., together with Apotex Corp., has filed an ANDA for a generic copy of Janssen's SYMTUZA® product, seeking approval from the FDA to market and sell the Apotex SYMTUZA ANDA Product, throughout the United States, including in Delaware. On information and belief, Apotex Inc. intends to commercially manufacture, use, and sell the Apotex SYMTUZA ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves the Apotex SYMTUZA ANDA, the Apotex SYMTUZA ANDA Product would, among other things, be marketed, distributed, and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing the Apotex SYMTUZA ANDA, Apotex Inc. has made clear that it intends to use its distribution channels to direct sales of the Apotex SYMTUZA ANDA Product into Delaware.

19. Further, this Court has personal jurisdiction over Apotex Inc. because it has previously been sued in this District and has not challenged personal jurisdiction, and Apotex Inc. has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District. *See, e.g., Gilead Sciences, Inc. v. Apotex Inc. et al.*, Civil Action No. 20-189, D.I. 28 (D. Del. Apr. 13, 2020); *Horizon Medicines LLC et al. v. Apotex Inc. et al.*, Civil Action No. 22-640, D.I. 35 (D. Del. June 28, 2022); *Galderma Laby's L.P. et al. v. Apotex Inc. et al.*, Civil Action No. 22-

724, D.I. 13 (D. Del. June 23, 2022); *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, Civil Action No. 21-1429, D.I. 14 (D. Del. Mar. 1, 2022); *Zogenix, Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 21-1533, D.I. 13 (D. Del. Jan. 3, 2022); *Bial-Portela & CA S.A. et al. v. Apotex Inc. et al.*, Civil Action No. 21-187, D.I. 6 (D. Del. Mar. 3, 2021); *Intercept Pharma., Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 20-1105, D.I. 10 (D. Del. Oct. 23, 2020); *UCB, Inc. et al. v. Annora Pharma Pvt. Ltd. et al.*, Civil Action No. 20-987, D.I. 33 (D. Del. Oct. 6, 2020); *Sanofi-Aventis U.S., LLC et al. v. Actavis LLC et al.*, Civil Action No. 20-804, D.I. 46 (D. Del. July 20, 2020); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, Civil Action No. 20-749, D.I. 7 (D. Del. June 26, 2020).

20. Alternatively, this Court may exercise personal jurisdiction over Apotex Inc. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Apotex Inc. is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Apotex Inc. has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

21. Venue is proper in this Court for Apotex Inc. under 28 U.S.C. § 1391(c)(3) because Apotex Inc. is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Apotex Corp.

22. On information and belief, this Court has personal jurisdiction over Apotex Corp. because, *inter alia*, it is incorporated in Delaware.

23. On information and belief, Apotex Corp. has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being subject to the jurisdiction of the court in the District of Delaware.

24. On information and belief, Apotex Corp., directly and/or through its parent company Apotex Inc., markets, distributes, and sells generic pharmaceutical products throughout the United States, including in this District.

25. On information and belief, Apotex Corp. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this District, directly and/or through its parent company Apotex Inc.

26. On information and belief, this Court also has personal jurisdiction because Apotex Corp., together with Apotex Inc., has filed an ANDA for a generic copy of Janssen's SYMTUZA® product, seeking approval from the FDA to market and sell the Apotex SYMTUZA ANDA Product, throughout the United States, including in Delaware. On information and belief, Apotex Corp. intends to commercially manufacture, use, and sell the Apotex SYMTUZA ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves the Apotex SYMTUZA ANDA, the Apotex SYMTUZA ANDA Product would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing the Apotex SYMTUZA ANDA, Apotex Corp. has made clear that it intends to use its distribution channels to direct sales of the Apotex SYMTUZA ANDA Product into Delaware.

27. Further, this Court has personal jurisdiction over Apotex Corp. because it has previously been sued in this District and has not challenged personal jurisdiction, and Apotex

Corp. has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District. *See, e.g., Horizon Medicines LLC et al. v. Apotex Inc. et al.*, Civil Action No. 22-640, D.I. 35 (D. Del. June 28, 2022); *Galderma Laby's L.P. et al. v. Apotex Inc. et al.*, Civil Action No. 22-724, D.I. 13 (D. Del. June 23, 2022); *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, Civil Action No. 21-1429, D.I. 14 (D. Del. Mar. 1, 2022); *Zogenix, Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 21-1533, D.I. 13 (D. Del. Jan. 3, 2022); *Bial-Portela & CA S.A. et al. v. Apotex Inc. et al.*, Civil Action No. 21-187, D.I. 6 (D. Del. Mar. 3, 2021); *Intercept Pharma., Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 20-1105, D.I. 10 (D. Del. Oct. 23, 2020); *UCB, Inc. et al. v. Annora Pharma Pvt. Ltd. et al.*, Civil Action No. 20-987, D.I. 33 (D. Del. Oct. 6, 2020); *Sanofi-Aventis U.S., LLC et al. v. Actavis LLC et al.*, Civil Action No. 20-804, D.I. 46 (D. Del. July 20, 2020); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, Civil Action No. 20-749, D.I. 7 (D. Del. June 26, 2020).

28. Venue is proper in this Court for Apotex Corp. under 28 U.S.C. § 1400(b) because, *inter alia*, Apotex Corp. is incorporated in Delaware.

PATENTS-IN-SUIT

29. On August 7, 2018, the U.S. Patent and Trademark Office duly and legally issued the '718 patent, titled, "Use of Solid Carrier Particles to Improve the Processability of A Pharmaceutical Agent." A true and correct copy of the '718 patent is attached hereto as Exhibit A. The claims of the '718 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '718 patent. Janssen is the exclusive licensee under the '718 patent for the commercialization of SYMTUZA®.

30. On September 29, 2020, the U.S. Patent and Trademark Office duly and legally issued the '518 patent, titled, "Compositions and Methods of Treating HIV." A true and correct

copy of the '518 patent is attached hereto as Exhibit B. The claims of the '518 patent are valid, enforceable, and not expired. Janssen Sciences Ireland Unlimited Company and Gilead Sciences, Inc. are the assignees of the '518 patent.

31. On July 30, 2013, the U.S. Patent and Trademark Office duly and legally issued the '396 patent, titled, "Methods and Intermediates for Preparing Pharmaceutical Agents." A true and correct copy of the '396 patent is attached hereto as Exhibit C. The claims of the '396 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '396 patent.

32. On August 30, 2016, the U.S. Patent and Trademark Office duly and legally issued the '473 patent, titled, "Methods and Intermediates for Preparing Pharmaceutical Agents." A true and correct copy of the '473 patent is attached hereto as Exhibit D. The claims of the '473 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '473 patent.

33. On August 25, 2015, the U.S. Patent and Trademark Office duly and legally issued the '100 patent, titled, "Methods and Intermediates for Preparing Pharmaceutical Agents." A true and correct copy of the '100 patent is attached hereto as Exhibit E. The claims of the '100 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '100 patent.

ACTS GIVING RISE TO THIS ACTION

SYMTUZA®

34. Janssen Products, LP holds approved NDA No. 210455 for tablets containing a four-drug combination of darunavir (DRV), a human immunodeficiency virus (HIV-1) protease inhibitor, cobicistat (COBI), a CYP3A inhibitor, and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors. The tablets are indicated as a complete regimen for the treatment of HIV-1 infection.

35. Janssen markets the tablets approved under NDA No. 210455 in the United States under the registered trademark SYMTUZA®. FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") identifies the Orange Book Patents-In-Suit, among other patents, for SYMTUZA®.

36. At least one claim of each of the Orange Book Patents-In-Suit covers SYMTUZA®, or approved methods of using SYMTUZA®. At least one claim of each of the COBI Patents-In-Suit covers a method of making COBI, a method of making a component of COBI, or an intermediate compound used in making COBI or a component of COBI.

37. Apotex submitted to FDA an ANDA listing SYMTUZA® as the reference listed drug ("RLD").

Apotex's Acts Regarding SYMTUZA®

38. On information and belief, Apotex, alone and with subsidiaries, affiliates, agents, and partners, submitted to FDA the Apotex SYMTUZA ANDA under Section 505(j) of the FDCA, seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Apotex SYMTUZA ANDA Product before the expiration of all four Patents-In-Suit. On information and belief, FDA assigned the ANDA number 217728.

39. On information and belief, Apotex sent a letter dated September 12, 2022 to Janssen and Gilead ("Apotex's SYMTUZA Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Apotex's SYMTUZA Notice Letter states that the Apotex SYMTUZA ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

40. Janssen and Gilead received the SYMTUZA Notice Letter on or about September 13.

41. Apotex's SYMTUZA Notice Letter does not contest infringement of the claims of the '718 patent.

42. This action is being commenced before the expiration of 45 days from the date Janssen and Gilead received Apotex's SYMTUZA Notice Letter, which triggers a stay of FDA approval of the Apotex SYMTUZA ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

43. By submitting the Apotex SYMTUZA ANDA, Apotex has represented to FDA that the Apotex SYMTUZA ANDA Product has the same active ingredients as SYMTUZA®; has the same dosage forms and strengths as SYMTUZA®; and is bioequivalent to SYMTUZA®.

44. On information and belief, Apotex's proposed label for its Apotex SYMTUZA ANDA Product (the "Proposed Label") will refer to the product as, *inter alia*, a four-drug combination of darunavir, cobicistat, emtricitabine, and tenofovir alafenamide, indicated as a complete regimen for the treatment of HIV-1 infection.

45. On information and belief, Apotex's Proposed Label will instruct physicians and healthcare providers to administer the Apotex SYMTUZA ANDA Product for the treatment of HIV-1 infection.

46. On information and belief, Apotex's Proposed Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving SYMTUZA®.

Plaintiffs' Attempts to Gain Access to Apotex's ANDA

47. Apotex's SYMTUZA Notice Letter included an Offer for Confidential Access ("OCA") to the Apotex SYMTUZA ANDA on terms and conditions set forth therein. The OCA requested that Plaintiffs accept the terms of the OCA before receiving access to the Apotex SYMTUZA ANDA. Under 35 U.S.C. 355(j)(5)(C)(i)(III), an OCA "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as

would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.” Apotex’s OCA contained unreasonable restrictions, above and beyond those that would apply under a protective order.

48. For example, the terms of Apotex’s OCA would have precluded Plaintiffs from bringing suit on patents that protect Janssen’s SYMTUZA® product. Although Plaintiffs explained orally and in writing that they could not agree to such an unreasonable restriction in the OCA and that an OCA cannot be used to preclude a lawsuit on patents that protect Janssen’s SYMTUZA® product, Apotex refused to modify the terms of its OCA.

49. Since receiving Apotex’s SYMTUZA Notice Letter, Plaintiffs have negotiated in good faith to reach a mutually-acceptable agreement under which Apotex would provide the Apotex SYMTUZA ANDA to Plaintiffs. To date, despite repeated follow-up on September 20, September 26, September 30, October 5, October 10 and October 14, Apotex has refused to offer Plaintiffs access to the Apotex SYMTUZA ANDA under terms consistent with a protective order entered for the purpose of protecting trade secrets and other confidential business information. As a result, Plaintiffs have been unable to access the Apotex SYMTUZA ANDA or any portion of the ANDA, including the Proposed Label, or the supporting Drug Master Files (DMFs) referred to and incorporated by reference into the Apotex SYMTUZA ANDA.

50. Plaintiffs informed Apotex that “if Apotex believes it does not infringe the Gilead/Janssen patents, it is in its interest to provide the requested materials.” But Apotex has refused to provide access to the materials on reasonable terms.

51. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV notice letter in order to receive certain

benefits under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate, pursuant to 21 U.S.C. § 355(c)(3)(C).

52. Plaintiffs are not aware of any other means of obtaining information regarding Apotex's ANDA Product within the 45-day statutory period. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief, and to present to the Court evidence, that Apotex has and will infringe certain claims of the Patents-In-Suit.

COUNTS I-VII FOR PATENT INFRINGEMENT

Count I: Infringement of the '718 Patent under 35 U.S.C. § 271(e)(2) by the Apotex SYMTUZA ANDA Product

53. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

54. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the '718 patent by submitting to FDA the Apotex SYMTUZA ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product in the United States prior to the expiration of the '718 patent.

55. Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product and/or components of the Apotex SYMTUZA ANDA Product prior to the expiration of the '718 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '718 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

56. Apotex's SYMTUZA Notice Letter does not dispute that Apotex infringes the claims of the '718 patent.

57. On information and belief, Apotex has actual knowledge of the '718 patent.

58. On information and belief, Apotex became aware of the '718 patent no later than the filing of its Apotex SYMTUZA ANDA.

59. The commercial manufacture, importation, use, sale, or offer for sale of the Apotex SYMTUZA ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

60. Unless and until Apotex is enjoined from infringing the '718 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

Count II: Declaratory Judgment of Infringement of the '718 Patent under 35 U.S.C. §§ 271(a)-(c) and/or (g) by the Apotex SYMTUZA ANDA Product

61. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

62. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

63. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution, and that actual case or controversy requires a declaration of rights by this Court.

64. Apotex has submitted to FDA an ANDA for a generic version of Janssen's SYMTUZA® product. According to Apotex's SYMTUZA Notice Letter, Apotex intends to commercially manufacture, use, offer for sale, sell, and/or import the Apotex SYMTUZA ANDA Product in or into the United States.

65. Although FDA has not approved the Apotex SYMTUZA ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, sell, offer to sell, and/or import the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of the Apotex SYMTUZA ANDA Product.

66. Apotex's actions indicate that it does not intend to change its course of conduct.

67. On information and belief, upon FDA approval of the Apotex SYMTUZA ANDA, Apotex will infringe one or more claims of the '718 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 5, and/or 14, by making, using, offering to sell, and/or selling the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of the Apotex SYMTUZA ANDA Product in the United States, and/or importing said product and/or component into the United States, and/or by actively inducing and contributing to infringement, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

68. Apotex's SYMTUZA Notice Letter does not dispute that Apotex infringes the claims of the '718 patent.

69. On information and belief, the Apotex SYMTUZA ANDA Product will include COBI on SiO₂ as a component.

70. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, Apotex will commercially manufacture, use, offer to sell, and/or sell the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of the Apotex SYMTUZA ANDA Product in the United States, and/or import said product and/or component into the United States.

71. Through at least the foregoing actions, Apotex will directly infringe one or more claims of the '718 patent under 35 U.S.C. § 271(a).

72. On information and belief, Apotex has actual knowledge of the '718 patent.

73. On information and belief, Apotex became aware of the '718 patent no later than the filing of its Apotex SYMTUZA ANDA.

74. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, the

commercial manufacture, use, offer to sell, and/or sale of the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of the Apotex SYMTUZA ANDA Product in the United States, and/or importation of said product and/or component into the United States will directly infringe one or more claims of the '718 patent.

75. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, Apotex will actively induce, encourage, aid and abet the commercial manufacture, use, offer for sale, and/or sale of the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of said product in the United States, and/or importation of said product and/or component into the United States, with knowledge and specific intent that the conduct infringes the '718 patent. On information and belief, this knowledge is reflected through, among other things, Apotex's SYMTUZA Notice Letter, which does not contest infringement of the claims of the '718 patent.

76. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '718 patent under 35 U.S.C. § 271(b).

77. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, Apotex knows that COBI and/or COBI on SiO₂ are especially made or adapted for use in infringing the '718 patent, *e.g.*, *e.g.*, by incorporating COBI and/or COBI on SiO₂ as a component of a composition claimed in the '718 patent, and that COBI and/or COBI on SiO₂ are not suitable for substantial non-infringing use.

78. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, the commercial manufacture, use, offer to sell, and/or sale of the Apotex SYMTUZA ANDA Product, and/or the COBI and/or COBI on SiO₂ components of the Apotex SYMTUZA ANDA

Product, in the United States, and/or the importation of said product and/or components into the United States will infringe the '718 patent.

79. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, Apotex's offer to sell and/or sale of the Apotex SYMTUZA ANDA Product, and/or the COBI and/or COBI on SiO₂ components of the Apotex SYMTUZA ANDA Product, in the United States, and/or the importation of said product and/or components into the United States will contribute to the actual infringement of the '718 patent.

80. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, Apotex knows that its offer to sell and/or sale of the Apotex SYMTUZA ANDA Product, and/or the COBI and/or COBI on SiO₂ components of the Apotex SYMTUZA ANDA Product, in the United States, and/or the importation of said product and/or components into the United States will contribute to the actual infringement of the '718 patent.

81. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '718 patent under 35 U.S.C. § 271(c).

82. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, Apotex will import a product made by a process claimed in the '718 patent into the United States and/or offer to sell, sell, or use that product in the United States.

83. On information and belief, the product made by a process claimed in the '718 patent will not be materially changed by a subsequent process nor will it become a trivial and nonessential component of another product.

84. Through at least the foregoing actions, Apotex will infringe at least one claim of the '718 patent under 35 U.S.C. § 271(g).

85. Plaintiffs are entitled to a declaratory judgment that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of said product in or into the United States, and/or Apotex's inducement and contribution to the same, prior to the expiration of the '718 patent will constitute infringement of the '718 patent.

86. The commercial manufacture, importation, use, sale, or offer for sale of the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of said product in or into the United States in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

87. Unless and until Apotex is enjoined from infringing the '718 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

**Count III: Infringement of the '518 Patent under 35 U.S.C. § 271(e)(2) by the
Apotex SYMTUZA ANDA Product**

88. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

89. Apotex refused to provide Plaintiffs with its Proposed Label on reasonable terms that would allow Plaintiffs to sue Apotex for infringement of the '518 patent.

90. On information and belief, if Apotex had a reasonable basis to contest infringement of the '518 patent, it would provide its Proposed Label and associated regulatory correspondence to Plaintiffs. Apotex did not do so.

91. On information and belief, pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the '518 patent by submitting to FDA the Apotex SYMTUZA ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or

importation of the Apotex SYMTUZA ANDA Product in the United States prior to the expiration of the '518 patent.

92. On information and belief, Apotex has actual knowledge of the '518 patent.

93. On information and belief, Apotex became aware of the '518 patent no later than the filing of its Apotex SYMTUZA ANDA.

94. On information and belief, including based on Apotex's failure to provide its Proposed Label, Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product prior to the expiration of the '518 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '518 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

95. The commercial manufacture, importation, use, sale, or offer for sale of the Apotex SYMTUZA ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

96. Unless and until Apotex is enjoined from infringing the '518 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

Count IV: Declaratory Judgment of Infringement of the '518 Patent under 35 U.S.C. §§ 271(b) and/or (c) by the Apotex SYMTUZA ANDA Product

97. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

98. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

99. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the U.S. Constitution, and that actual case or controversy requires a declaration of rights by this Court.

100. Apotex has submitted to FDA an ANDA for a generic copy of Janssen's SYMTUZA® product. According to Apotex's SYMTUZA Notice Letter, Apotex intends to commercially manufacture, use, offer for sale, sell, and/or import the Apotex SYMTUZA ANDA Product within the United States.

101. Although FDA has not approved the Apotex SYMTUZA ANDA, Apotex has made, and will continue to make, substantial preparations in the United States to manufacture, use, sell, offer to sell, and/or import the Apotex SYMTUZA ANDA Product.

102. Apotex's actions indicate that it does not intend to change its course of conduct.

103. On information and belief, including due to Apotex's failure to provide its Proposed Label, upon FDA approval of the Apotex SYMTUZA ANDA, Apotex will infringe one or more claims of the '518 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, by making, using, offering to sell, and/or selling the Apotex SYMTUZA ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '518 patent by others, under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

104. On information and belief, Apotex has actual knowledge of the '518 patent.

105. On information and belief, Apotex became aware of the '518 patent no later than the filing of its Apotex SYMTUZA ANDA.

106. On information and belief, Apotex's efforts to make, use, sell, offer for sell, and/or import the Apotex SYMTUZA ANDA Product have been made and will be made with full knowledge of the '518 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '518 patent. On information

and belief, this knowledge is reflected through, among other things, Apotex's failure to provide Plaintiffs with its Proposed Label.

107. On information and belief, the Apotex SYMTUZA ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Apotex in the United States or on its behalf.

108. On information and belief, the Proposed Label will include directions and instructions that instruct physicians and healthcare providers to administer the Apotex SYMTUZA ANDA Product in order to treat HIV-1 in accordance with the methods described and claimed in the '518 patent.

109. On information and belief, physicians and healthcare providers will administer the Apotex SYMTUZA ANDA Product in the United States according to the directions and instructions in the Proposed Label, and such administration will constitute direct infringement of at least one claim of the '518 patent.

110. On information and belief, at least through the Proposed Label, Apotex will encourage physicians and healthcare providers to administer the Apotex SYMTUZA ANDA Product in order to treat HIV-1 in accordance with the methods described and claimed in the '518 patent, and Apotex will know or should know that such conduct will occur.

111. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringes the '518 patent.

112. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '518 patent under 35 U.S.C. § 271(b).

113. On information and belief, Apotex knows or should know that the Apotex SYMTUZA ANDA Product will be especially made or adapted for use in infringing the '518 patent and that the Apotex SYMTUZA ANDA Product is not suitable for substantial non-infringing use.

114. The commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex SYMTUZA ANDA Product will contribute to the actual infringement of the '518 patent.

115. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of the Apotex SYMTUZA ANDA Product will contribute to the actual infringement of the '518 patent.

116. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '518 patent under 35 U.S.C. § 271(c).

117. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product by Apotex prior to the expiration of the '518 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '518 patent.

118. The commercial manufacture, importation, use, sale, or offer for sale of the Apotex SYMTUZA ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

119. Unless and until Apotex is enjoined from infringing the '518 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

Count V: Declaratory Judgment of Infringement of the '396 Patent under 35 U.S.C. §§ 271(a)-(c) and/or (g) by the Apotex SYMTUZA ANDA Product

120. Gilead realleges the foregoing paragraphs as if fully set forth herein.

121. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

122. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the U.S. Constitution, and that actual case or controversy requires a declaration of rights by this Court.

123. Apotex has submitted to FDA an ANDA for a generic copy of Janssen's SYMTUZA® product. According to Apotex's SYMTUZA Notice Letter, Apotex intends to commercially manufacture, use, offer for sale, sell, and/or import the Apotex SYMTUZA ANDA Product within the United States.

124. Although FDA has not approved the Apotex SYMTUZA ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Apotex SYMTUZA ANDA Product and/or components of the Apotex SYMTUZA ANDA Product.

125. Apotex's actions indicate that it does not intend to change its course of conduct.

126. On information and belief, including due to Apotex's failure to provide the Apotex SYMTUZA ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, Apotex will infringe one or more claims of the '396 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and/or 2, by using a process claimed in the '396 patent in the United States, and/or using, offering to sell, and/or selling a product made by a process claimed in the '396 patent in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), and will continue to do so unless enjoined by the Court.

127. On information and belief, the Apotex SYMTUZA ANDA Product will include COBI as a component.

128. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, Apotex will commercially manufacture the Apotex SYMTUZA ANDA Product and/or the COBI component of the Apotex SYMTUZA ANDA Product in the United States according to a process claimed in the '396 patent.

129. Through at least the foregoing actions, Apotex will directly infringe one or more claims of the '396 patent under 35 U.S.C. § 271(a).

130. On information and belief, Apotex has actual knowledge of the '396 patent.

131. On information and belief, Apotex became aware of the '396 patent no later than the filing of its Apotex SYMTUZA ANDA.

132. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, the commercial manufacture of the Apotex SYMTUZA ANDA Product and/or the COBI component of said product in the United States according to a process claimed in the '396 patent, will directly infringe one or more claims of the '396 patent.

133. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, Apotex will actively induce, encourage, aid and abet the commercial manufacture of the Apotex SYMTUZA ANDA Product and/or the COBI component of said product in the United States according to a process claimed in the '396 patent with knowledge and specific intent that the conduct infringes the '396 patent.

134. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '396 patent under 35 U.S.C. § 271(b).

135. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, Apotex will offer to sell, and/or sell in the United States, and/or import into the United States a material for use in a process claimed in the '396 patent, knowing that said material will be especially made or adapted for use in infringing the '396 patent and that said material is not suitable for substantial non-infringing use.

136. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '396 patent under 35 U.S.C. § 271(c).

137. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, Apotex will import a product made by a process claimed in the '396 patent into the United States and/or offer to sell, sell, or use that product in the United States.

138. On information and belief, the product made by a process claimed in the '396 patent will not be materially changed by a subsequent process nor will it become a trivial and nonessential component of another product.

139. Through at least the foregoing actions, Apotex will infringe at least one claim of the '396 patent under 35 U.S.C. § 271(g).

140. Gilead is entitled to a declaratory judgment that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product and/or the COBI component of said product in or into the United States, and/or Apotex's inducement and contribution to the same, prior to the expiration of the '396 patent will constitute infringement of the '396 patent.

141. The commercial manufacture, importation, use, sale, or offer for sale of the Apotex SYMTUZA ANDA Product and/or the COBI component of said product in or into the United States in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

142. Unless and until Apotex is enjoined from infringing the '396 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count VI: Declaratory Judgment of Infringement of the '473 Patent under 35 U.S.C. §§ 271(a)-(c) and/or (g) by the Apotex SYMTUZA ANDA Product

143. Gilead realleges the foregoing paragraphs as if fully set forth herein.

144. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

145. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the U.S. Constitution, and that actual case or controversy requires a declaration of rights by this Court.

146. Apotex has submitted to FDA an ANDA for a generic copy of Janssen's SYMTUZA® product. According to Apotex's SYMTUZA Notice Letter, Apotex intends to manufacture, use, offer for sale, sell, and/or import the Apotex SYMTUZA ANDA Product within the United States.

147. Although FDA has not approved the Apotex SYMTUZA ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to use, sell, offer to sell, and/or import the Apotex SYMTUZA ANDA Product and/or components of the Apotex SYMTUZA ANDA Product.

148. Apotex's actions indicate that it does not intend to change its course of conduct.

149. On information and belief, upon FDA approval of the Apotex SYMTUZA ANDA, Apotex will infringe one or more claims of the '473 patent, either literally or under the doctrine of

equivalents, including but not limited to claims 1, 9, and/or 16, by making, using, offering to sell, and/or selling the Apotex SYMTUZA ANDA Product and/or the COBI component of the Apotex SYMTUZA ANDA Product in the United States, and/or importing said product and/or component into the United States, and/or by actively inducing and contributing to infringement, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

150. On information and belief, the Apotex SYMTUZA ANDA Product will include COBI as a component.

151. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, Apotex will commercially manufacture, use, offer to sell, and/or sell the Apotex SYMTUZA ANDA Product and/or the COBI component of the Apotex SYMTUZA ANDA Product in the United States, and/or import said product and/or component into the United States.

152. Through at least the foregoing actions, Apotex will directly infringe one or more claims of the '473 patent under 35 U.S.C. § 271(a).

153. On information and belief, Apotex has actual knowledge of the '473 patent.

154. On information and belief, Apotex became aware of the '473 patent no later than the filing of its Apotex SYMTUZA ANDA.

155. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, the commercial manufacture, use, offer to sell, and/or sale of the Apotex SYMTUZA ANDA Product and/or the COBI component of the Apotex SYMTUZA ANDA Product in the United States, and/or importation of said product and/or component into the United States will directly infringe one or more claims of the '473 patent.

156. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, Apotex will actively induce, encourage, aid and abet the commercial manufacture, use, offer for sale, and/or sale of the Apotex SYMTUZA ANDA Product and/or the COBI component of said product in the United States, and/or importation of said product and/or component into the United States, with knowledge and specific intent that the conduct infringes the '473 patent.

157. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '473 patent under 35 U.S.C. § 271(b).

158. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, Apotex will offer to sell, and/or sell in the United States, and/or import into the United States a component and/or material for use according to the claims of the '473 patent, knowing that said component and/or material will be especially made or adapted for use in infringing the '473 patent and that said component and/or material is not suitable for substantial non-infringing use.

159. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '473 patent under 35 U.S.C. § 271(c).

160. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, Apotex will import a product made by a process claimed in the '473 patent into the United States and/or offer to sell, sell, or use that product in the United States.

161. On information and belief, the product made by a process claimed in the '473 patent will not be materially changed by a subsequent process nor will it become a trivial and nonessential component of another product.

162. Through at least the foregoing actions, Apotex will infringe at least one claim of the '473 patent under 35 U.S.C. § 271(g).

163. Gilead is entitled to a declaratory judgment that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product and/or the COBI component of said product in or into the United States, and/or Apotex's inducement and contribution to the same, prior to the expiration of the '473 patent will constitute infringement of the '473 patent.

164. The commercial manufacture, importation, use, sale, or offer for sale of the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of said product in or into the United States in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

165. Unless and until Apotex is enjoined from infringing the '473 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count VII: Declaratory Judgment of Infringement of the '100 Patent under 35 U.S.C. §§ 271(a)-(c) by the Apotex SYMTUZA ANDA Product

166. Gilead realleges the foregoing paragraphs as if fully set forth herein.

167. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

168. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the U.S. Constitution, and that actual case or controversy requires a declaration of rights by this Court.

169. Apotex has submitted to FDA an ANDA for a generic copy of Janssen's SYMTUZA® product. According to Apotex's SYMTUZA Notice Letter, Apotex intends to commercially manufacture, use, offer for sale, sell, and/or import the Apotex SYMTUZA ANDA Product within the United States.

170. Although FDA has not approved the Apotex SYMTUZA ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to use, sell, offer to sell, and/or import the Apotex SYMTUZA ANDA Product and/or components of the Apotex SYMTUZA ANDA Product.

171. Apotex's actions indicate that it does not intend to change its course of conduct.

172. On information and belief, upon FDA approval of the Apotex SYMTUZA ANDA, Apotex will infringe one or more claims of the '100 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 to 4, by making, using, offering to sell, and/or selling the Apotex SYMTUZA ANDA Product and/or the COBI component of the Apotex SYMTUZA ANDA Product in the United States, and/or importing said product and/or component into the United States, and/or by actively inducing and contributing to infringement, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

173. On information and belief, the Apotex SYMTUZA ANDA Product will include COBI as a component.

174. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, Apotex will commercially manufacture, use, offer to sell, and/or sell the Apotex SYMTUZA ANDA Product and/or the COBI component of the Apotex SYMTUZA ANDA Product in the United States, and/or import said product and/or component into the United States.

175. Through at least the foregoing actions, Apotex will directly infringe one or more claims of the '100 patent under 35 U.S.C. § 271(a).

176. On information and belief, Apotex has actual knowledge of the '100 patent.

177. On information and belief, Apotex became aware of the '100 patent no later than the filing of its Apotex SYMTUZA ANDA.

178. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by FDA, the commercial manufacture, use, offer to sell, and/or sale of the Apotex SYMTUZA ANDA Product and/or the COBI component of the Apotex SYMTUZA ANDA Product in the United States, and/or importation of said product and/or component into the United States will directly infringe one or more claims of the '100 patent.

179. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, Apotex will actively induce, encourage, aid and abet the commercial manufacture, use, offer for sale, and/or sale of the Apotex SYMTUZA ANDA Product and/or the COBI component of said product in the United States, and/or importation of said product and/or component into the United States, with knowledge and specific intent that the conduct infringes the '100 patent.

180. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '100 patent under 35 U.S.C. § 271(b).

181. On information and belief, including due to Apotex's failure to provide the Symtuza ANDA or the DMF for COBI on SiO₂, if the Apotex SYMTUZA ANDA is approved by the FDA, Apotex will offer to sell, and/or sell in the United States, and/or import into the United States a component of the claims of the '100 patent, knowing that said component will be especially made or adapted for use in infringing the '100 patent and that said component is not suitable for substantial non-infringing use.

182. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '100 patent under 35 U.S.C. § 271(c).

183. Gilead is entitled to a declaratory judgment that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product and/or the COBI component of said product in or into the United States, and/or Apotex's inducement and contribution to the same, prior to the expiration of the '100 patent will constitute infringement of the '100 patent.

184. The commercial manufacture, importation, use, sale, or offer for sale of the Apotex SYMTUZA ANDA Product and/or the COBI on SiO₂ component of said product in or into the United States in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

185. Unless and until Apotex is enjoined from infringing the '100 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A) A judgment that Apotex has infringed the '718 patent and the '518 patent under 35 U.S.C. § 271(e)(2)(A);

B) A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex SYMTUZA ANDA shall be a date which is not earlier than the day after the latest expiration date of the '718 patent and the '518 patent as extended by any applicable periods of exclusivity to which Plaintiffs are or will be entitled;

C) A judgment declaring that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex SYMTUZA ANDA Product and/or components of the

Apotex SYMTUZA ANDA Product in or into the United States prior to the expiration of the '718 patent, '518 patent, '396 patent, '473 patent, and '100 patent (including such actions by its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Apotex or acting on Apotex's behalf) will constitute infringement of the '718 patent, '518 patent, '396 patent, '473 patent, and '100 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

D) An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Apotex, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, and/or selling in the United States, and/or importing into the United States, the Apotex SYMTUZA ANDA Product until the day after the latest expiration date of the '718 patent, '518 patent, '396 patent, '473 patent, and '100 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or will be entitled, and from otherwise infringing one or more claims of the '718 patent, '518 patent, '396 patent, '473 patent, and '100 patent;

E) A declaration that this case is exceptional;

F) An award of Plaintiffs' costs, expenses, reasonable attorneys' fees and such other relief as the Court deems proper and just pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

G) Such other and further relief as this Court deems just and proper.

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